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L1: Entry 2 of 2 File: USPT Oct 3, 1995

US-PAT-NO: 5455031
DOCUMENT-IDENTIFIER: US 5455031 A
** See image for Certificate of Correction **

TITLE: Polypeptide with 46 Kdalton HMFG differentiation antigen binding specificity, composition, kit and diagnostic method

DATE-ISSUED: October 3, 1995

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Ceriani; Roberto L.	Lafayette	CA		
Peterson; Jerry A.	Lafayette	CA		
Larocca; David J.	San Leandro	CA		

US-CL-CURRENT: 424/185.1; 424/184.1, 435/7.1, 530/350

CLAIMS:

We claim:

1. A purified, isolated polypeptide having the antibody binding specificity of the about 46 Kdalton human milk fat globule (HMFG) differentiation antigen.

2. The polypeptide of claim 1, being the about 46 Kdalton HMFG differentiation antigen or an antibody binding 218 amino acids long fragment thereof.

3. A composition, comprising an antibody binding effective amount of the polypeptide of claim 1, and a pharmaceutically acceptable carrier.

4. A method of detecting the presence in a biological sample of an antibody having affinity for the about 46 Kdalton human milk fat globule (HMFG) differentiation antigen, comprising

obtaining a sample suspected of comprising the antibody;

adding thereto an antibody binding effective amount of the polypeptide of claim 1 under conditions effective to form an antibody-polypeptide complex; and

determining the presence of any complex formed.

5. An antibody detecting kit comprising, in separate containers the polypeptide of claim 1; and anti-antibody immunoglobulin.

6. The polypeptide of claim 1, comprising at least one peptide fragment having sequence similarity to at least a portion of the C1 or C2 domains of clotting factor V or VIII.

First Hit Fwd Refs

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L1: Entry 1 of 2 File: USPT Oct 26, 1999

US-PAT-NO: 5972337
DOCUMENT-IDENTIFIER: US 5972337 A

TITLE: 46 kilodalton human milk fat globule (HMFG) antigen, fragments and fusion protein

DATE-ISSUED: October 26, 1999

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Ceriani; Robeto L.	Lafayette	CA		
Peterson; Jerry A.	Lafayette	CA		
Larocca; David J.	Encinitas	CA		

US-CL-CURRENT: 424/185.1; 424/192.1, 530/300, 530/329, 530/350, 530/402

CLAIMS:

What is claimed as novel and unobvious in Letters Patent of the United States is:

1. A purified, isolated polypeptide consisting of

an amino acid sequence encoded by a nucleic acid consisting of a sequence selected from the group consisting of nucleotides 1-1221 of SEQ. ID No: 7 and nucleotides 1-654 of SEQ. ID No: 1;

hexapeptides comprising six contiguous amino acid residues from 332 to 382 of SEQ. ID NO:6; and

an amino acid sequence encoded by nucleotides 64-1221 of SEQ. ID No: 7 in non-denatured form.

2. The polypeptide of claim 1, consisting of the amino acid sequence encoded by nucleotides 64-1221 of SEQ. ID No: 7 in non-denatured form.

3. The polypeptide of claim 1, consisting of an amino acid sequence selected from the group consisting of the amino acid sequence encoded by nucleotides 1-654 of SEQ. ID No: 1 and the amino acid sequence encoded by nucleotides 1-1221 of SEQ. ID NO:7.

4. The polypeptide of claim 1, consisting of the amino acid sequence encoded by nucleotides 1-1221 of SEQ. ID NO:7.

5. The polypeptide of claim 1, in glycosylated form.

6. The polypeptide of claim 1, in unglycosylated form.

7. The polypeptide of claim 1, consisting of an amino acid sequence selected from the group consisting of amino acids 22-387 of SEQ. ID No: 6, SEQ. ID No: 2, SEQ. ID No: 3, and SEQ. ID NO:6 in non-denatured form.

8. The polypeptide of claim 7, consisting of SEQ. ID No: 6 in non-denatured form.

9. The polypcptide of claim 7, consisting of amino acids 22-387 of SEQ. ID No: 6.

10. The polypeptide of claim 7, consisting of SEQ. ID No: 2.

11. The polypeptide of claim 7, consisting of SEQ. ID No: 3.

12. A composition, comprising the polypeptide of claim 1, and a non-proteolytic carrier.

13. The composition of claim 12, wherein the non-proteolytic carrier comprises a biologically acceptable carrier.

14. The composition of claim 13, wherein the biologically acceptable carrier comprises a pharmaceutically acceptable carrier.

15. A fusion protein, comprising an amino acid sequence of the polypeptide of claim 1 linked to a peptide unrelated to the HMFG differentiation antigen.

16. The fusion protein of claim 15, wherein the peptide is about 10 to 1,000 amino acids long.

17. The fusion protein of claim 15, in unglycosylated form.

18. The fusion protein of claim 15, in unglycosylated form.

19. A composition, comprising the fusion protein of claim 15, and a non proteolytic carrier.

20. The composition of claim 19, wherein the carrier comprises a biologically acceptable carrier.

21. The composition of claim 19, wherein the carrier comprises a pharmaceutically acceptable carrier.

22. The polypeptide of claim 1, consisting of a hexapeptide comprising six contiguous amino acid residues from 332 to 382 of SEQ. ID NO:6.

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SYSTEM:OS  - DIALOG OneSearch
  File 155:MEDLINE(R) 1966-2004/Jun W1
         (c) format only 2004 The Dialog Corp.
*File 155: Medline has been reloaded. Accession numbers
have changed. Please see HELP NEWS 154 for details.
  File  55:Biosis Previews(R) 1993-2004/Jun W1
         (c) 2004 BIOSIS
  File  34:SciSearch(R) Cited Ref Sci 1990-2004/Jun W1
         (c) 2004 Inst for Sci Info
  File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
         (c) 1998 Inst for Sci Info
  File 340:CLAIMS(R)/US Patent 1950-04/Jun 10
         (c) 2004 IFI/CLAIMS(R)

      Set  Items  Description
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? s human(5n)milk(w)fat(w)globule
Processing
        12957868  HUMAN
          188441  MILK
          271021  FAT
           11926  GLOBULE
      S1     515  HUMAN(5N)MILK(W)FAT(W)GLOBULE
? s cancer? or tumor? or malignan?
Processing
         1379286  CANCER?
         1727957  TUMOR?
          531507  MALIGNAN?
      S2 2807597  CANCER? OR TUMOR? OR MALIGNAN?
? s s1 and s2
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         2807597  S2
      S3     341  S1 AND S2
? s 46
      S4  437154  46
? s s3 and s4
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          437154  S4
      S5      22  S3 AND S4
? s s5 and py<=1990
Processing
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        19204590  PY<=1990
      S6       4  S5 AND PY<=1990
? rd
>>>Duplicate detection is not supported for File 340.

>>>Records from unsupported files will be retained in the RD set.
...completed examining records
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? t s7/3,k,ab/1-4

 7/3,K,AB/1     (Item 1 from file: 155)
DIALOG(R)File 155:MEDLINE(R)
(c) format only 2004 The Dialog Corp. All rts. reserv.

08642434   PMID: 2393862
  Cloning  and sequencing of a complementary DNA encoding a Mr 70,000 human
breast epithelial mucin-associated antigen.
  Larocca D; Peterson J A; Walkup G; Urrea R; Ceriani R L
  John Muir Cancer and Aging Research Institute, Walnut Creek, CA 94596.
  Cancer research (UNITED STATES)   Sep 15 1990,  50  (18)  p5925-30,
ISSN 0008-5472   Journal Code: 2984705R
```

Contract/Grant No.: CA 39932; CA; NCI; CA42767; CA; NCI; RR05929; RR; NCRR
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

The **human milk fat globule** (HMFG) membrane contains several glycoproteins that have been referred to as breast differentiation antigens and that are expressed in normal breast, breast **tumors**, breast **tumor** -derived cell lines, and are found in breast **cancer** patient serum. These antigens include a high molecular weight mucin and several smaller components including Mr 150,000; 70,000; and **46**,000 glycoproteins. We have used 2 monoclonal antibodies (McR2 and Mc13) that bind the Mr 70,000 component of HMFG to immunoscreen a lambda gt11 expression library prepared from human lactating breast tissue. We report here the sequence of a complementary DNA clone (BA70-1) that codes for a peptide that binds both McR2 and Mc13 but not monoclonal antibodies to the breast mucin or other components of HMFG.A 1.8-kilobase RNA was detected in 9 of 9 breast **tumor** cell lines using 32P-labeled BA70-1 as probe. The BA70-1 RNA was highly expressed in 6 of 9 cells lines of breast and several other carcinomas lines compared with a lymphoblastoid cell line (Raji). The BA70-1 complementary DNA sequence has no extensive homology with previously reported sequences including the high-molecular weight mucin complementary DNA. Since the Mr 70,000 molecule appears to be associated with the breast mucin by disulfide bonds, its study could help elucidate the structure of this latter complex and how it is organized in the cell membrane, and prove useful in diagnosis and therapy of breast **cancer**.

Sep 15 **1990**,

The **human milk fat globule** (HMFG) membrane contains several glycoproteins that have been referred to as breast differentiation antigens and that are expressed in normal breast, breast **tumors**, breast **tumor** -derived cell lines, and are found in breast **cancer** patient serum. These antigens include a high molecular weight mucin and several smaller components including Mr 150,000; 70,000; and **46**,000 glycoproteins. We have used 2 monoclonal antibodies (McR2 and Mc13) that bind the Mr...

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... is organized in the cell membrane, and prove useful in diagnosis and therapy of breast **cancer**.

7/3,K,AB/2 (Item 2 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

08582712 PMID: 2365381

Biochemical and histological characterization of antigens preferentially expressed on the surface and cytoplasm of breast carcinoma cells identified by monoclonal antibodies against the **human milk fat globule**.

Peterson J A; Zava D T; Duwe A K; Blank E W; Battifora H; Ceriani R L
John Muir Cancer and Aging Research Institute, Walnut Creek, CA.

Hybridoma (UNITED STATES) Jun **1990**, 9 (3) p221-35, ISSN 0272-457X Journal Code: 8202424
Contract/Grant No.: CA39931; CA; NCI; CA39932; CA; NCI; RR05929; RR; NCRR
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM

Record type: Completed

The preparation of monoclonal antibodies (MAbs) against the **human milk fat globule** membrane with preferential binding to breast carcinoma cells is described. Using BALB/c mouse myeloma cells; inter-specific, intra-strain, and inter-strain hybridomas were isolated that identified three different components of the **human milk fat globule** of approximately **46**,000, and 70,000 daltons and a mucin-like glycoprotein complex (NPGP) ranging from 400,000 to over a million daltons, respectively. Three MAbs (BrE1, BrE2, BrE3) identified the latter component which consists of at least three different size molecules for which the aforementioned MAb's have different binding specificities. MAbs, BrE2 and BrE3, bound to normal breast epithelial cells but to a lesser extent than to **tumors** and only at the apical surface facing the lumen, while they bound breast carcinomas strongly, and often in the cytoplasm as well as on the surface. Higher concentrations of BrE3 were required to stain normal breast compared to breast **tumors**. BrE1 also stained breast carcinomas both on the surface and cytoplasmically but did not stain normal breast tissue. The MAb, Mc13, as well as the previously reported MAb McR2, both against the 70,000 dalton component, did not significantly stain either normal or **cancerous** breast tissue in histological sections but did bind significantly to cultured breast epithelial cells and to the milk fat globule membrane. The MAbs, Mc8 and Mc3, reported previously to be against the **46**,000 dalton component, stained histologically only **malignant** breast tissue but only weakly; however, they bound strongly to intact breast carcinoma cells and breast cell membrane preparations with a radioimmunobinding assay. These MAbs should be useful in characterizing the surface of breast epithelial cells, studying surface alterations in **malignancy**, and possibly in breast **cancer** diagnosis and therapy.

... on the surface and cytoplasm of breast carcinoma cells identified by monoclonal antibodies against the **human milk fat globule**.

Jun **1990**,

The preparation of monoclonal antibodies (MAbs) against the **human milk fat globule** membrane with preferential binding to breast carcinoma cells is described. Using BALB/c mouse myeloma...

... intra-strain, and inter-strain hybridomas were isolated that identified three different components of the **human milk fat globule** of approximately **46** ,000, and 70,000 daltons and a mucin-like glycoprotein complex (NPGP) ranging from 400...

...and BrE3, bound to normal breast epithelial cells but to a lesser extent than to **tumors** and only at the apical surface facing the lumen, while they bound breast carcinomas strongly...

...the surface. Higher concentrations of BrE3 were required to stain normal breast compared to breast **tumors**. BrE1 also stained breast carcinomas both on the surface and cytoplasmically but did not stain...

... McR2, both against the 70,000 dalton component, did not significantly stain either normal or **cancerous** breast tissue in histological sections but did bind significantly to cultured breast epithelial cells and ...

...milk fat globule membrane. The MAbs, Mc8 and Mc3, reported previously to be against the **46**,000 dalton component, stained histologically only **malignant** breast tissue but only weakly; however, they bound strongly to intact breast carcinoma cells and...

... should be useful in characterizing the surface of breast epithelial cells, studying surface alterations in **malignancy**, and possibly in breast **cancer** diagnosis and therapy.

7/3,K,AB/3 (Item 3 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

06257729 PMID: 6353626
Characterization of cell surface antigens of human mammary epithelial cells with monoclonal antibodies prepared against **human milk fat globule**.
Ceriani R L; Peterson J A; Lee J Y; Moncada R; Blank E W
Somatic cell genetics (UNITED STATES) Jul **1983**, 9 (4) p415-27, ISSN 0098-0366 Journal Code: 7506054
Contract/Grant No.: CA-19455; CA; NCI; RR 05467; RR; NCRR
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed
Hybridomas have been prepared that secrete monoclonal antibodies against three different surface antigens of normal human mammary epithelial cells by fusion of mouse myeloma cells with spleen cells from mice and rats immunized with delipidated human milk fat globules. Using a novel method for molecular weight determination, the three different monoclonal antibodies, BLMRL-HMFG-Mc3, BLMRL-HMFG-McR2, and BLMRL-HMFG-Mc5, were found to identify molecules with apparent molecular weights of **46**,000, 70,000, and 400,000 daltons, respectively. The latter is a mucin-like glycoprotein with a high sugar content and has not previously been described as a component of the **human milk fat globule** or of **human** mammary epithelial cell membranes. Single-cell quantitation of binding of monoclonal BLMRL-HMFG-Mc5 to three breast **tumor** cell lines using a Microscope Spectrum Analyzer and indirect immunofluorescence revealed a heterogeneous expression. Further, using a competitive radioimmunoassay, it was found that breast **tumor** cell lines differed by at least 10-fold in the 400,000-molecular-weight antigen content. None of the three antigens are detectable on several nonbreast cell lines, including normal breast fibroblasts.

Characterization of cell surface antigens of human mammary epithelial cells with monoclonal antibodies prepared against **human milk fat globule**.
Jul **1983**,
... McR2, and BLMRL-HMFG-Mc5, were found to identify molecules with apparent molecular weights of **46**,000, 70,000, and 400,000 daltons, respectively. The latter is a mucin-like glycoprotein...

... a high sugar content and has not previously been described as a component of the **human milk fat globule** or of **human** mammary epithelial cell membranes. Single-cell quantitation of binding of monoclonal BLMRL-HMFG-Mc5 to three breast **tumor** cell lines using a Microscope Spectrum Analyzer and indirect immunofluorescence revealed a heterogeneous expression. Further, using a competitive radioimmunoassay, it was found that breast **tumor** cell lines differed by at least 10-fold in the 400,000-molecular-weight antigen...

7/3,K,AB/4 (Item 4 from file: 155)
DIALOG(R)File 155:MEDLINE(R)

05972600 PMID: 6957872
Circulating human mammary epithelial antigens in breast **cancer**.
Ceriani R L; Sasaki M; Sussman H; Wara W M; Blank E W
Proceedings of the National Academy of Sciences of the United States of America (UNITED STATES) Sep **1982**, 79 (17) p5420-4, ISSN 0027-8424 Journal Code: 7505876

6/16/

Contract/Grant No.: CA 13533; CA; NCI; CA 19455; CA; NCI; CA 20286; CA; NCI
Document type: Journal Article
Languages: ENGLISH
Main Citation Owner: NLM
Record type: Completed

Heterologous specific antisera against human mammary epithelial antigens (HME-Ags), which are present in the **human milk fat globule** membrane and breast epithelial cells, were used in a solid-phase radioimmunoassay to determine the presence of these antigens in the sera of patients with disseminated **cancer** of the breast and other organs. Breast **cancer** patients carry high levels of HME-Ags in their circulation, while patients with disseminated nonbreast **cancer**, as well as normal female controls, do not. A similar release of HME-Ags in the circulation was shown by us in a model system. To further corroborate these findings, a three-step procedure for the extraction and identification of HME-Ags from the sera was devised. In this analytical procedure, circulating HME-Ags are recovered on a solid phase carrying their corresponding antibody (anti-HME) and radioiodinated in situ. Later, the labeled HME-Ags are released from the solid phase and characterized by NaDodSO4 gel electrophoresis. With this procedure, HME-Ags were isolated from sera of breast **cancer** patients but not from sera of nonbreast **cancer** patients or of normal female controls. The extracted HME-Ags had molecular masses of 150,000, 70,000, and **46**,000 daltons. To further support these findings, a monoclonal antibody, BLMRL-HMFG-Mc3, directed to the **46** ,000-dalton HME-Ag was also used to extract its corresponding antigen from sera. Breast **cancer** patient sera contained such antigen while the sera of the other patients and controls did not. This highly sensitive methodology offers a specific approach to breast **cancer** diagnosis as well as further insight into the nature of circulating antigens with a view to increasing our understanding of breast **cancer** biology.

Circulating human mammary epithelial antigens in breast **cancer**.
Sep **1982**,

Heterologous specific antisera against human mammary epithelial antigens (HME-Ags), which are present in the **human milk fat globule** membrane and breast epithelial cells, were used in a solid-phase radioimmunoassay to determine the presence of these antigens in the sera of patients with disseminated **cancer** of the breast and other organs. Breast **cancer** patients carry high levels of HME-Ags in their circulation, while patients with disseminated nonbreast **cancer**, as well as normal female controls, do not. A similar release of HME-Ags in...

... by NaDodSO4 gel electrophoresis. With this procedure, HME-Ags were isolated from sera of breast **cancer** patients but not from sera of nonbreast **cancer** patients or of normal female controls. The extracted HME-Ags had molecular masses of 150,000, 70,000, and **46**,000 daltons. To further support these findings, a monoclonal antibody, BLMRL-HMFG-Mc3, directed to the **46** ,000-dalton HME-Ag was also used to extract its corresponding antigen from sera. Breast **cancer** patient sera contained such antigen while the sera of the other patients and controls did not. This highly sensitive methodology offers a specific approach to breast **cancer** diagnosis as well as further insight into the nature of circulating antigens with a view to increasing our understanding of breast **cancer** biology.
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